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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/726,963

12/03/2003

David Ernest Hartley

PA-5351-RFB

4386

9896

7590

03/03/2010

COOK GROUP PATENT OFFICE

P.O. BOX 2269

BLOOMINGTON, IN 47402

EXAMINER

SEVERSON, RYAN J

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

03/03/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                       |  |
|------------------------------|--------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/726,963 | <b>Applicant(s)</b><br>HARTLEY ET AL. |  |
|                              | <b>Examiner</b><br>Ryan J. Severson  | <b>Art Unit</b><br>3731               |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,6,7,9,17,18 and 20-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,6,7,9,17,18 and 20-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 recites a new limitation stating the threads or fibers extending in a zig zag manner. Examiner can not find any support for such a limitation. The specification merely states that threads or fibers may be used to connect adjacent stents, but does not describe them extending in a zig zag manner.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. **Claims 1, 2, 6, 9, 17, 18, 20, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brightbill (2003/0204245) in view of Cox et al. (5,824,040).**  
Brightbill discloses a prosthesis comprising a graft-covered stent portion (120, see paragraph [0023]) comprising at least 3 stents (110) that are zig-zag shaped and self-

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expanding stainless steel or nitinol (see paragraph [0024]). The prosthesis also has an uncovered stent portion (140, see paragraph [0026]) being the same shape and material as the covered stents. However, Brightbill fails to disclose flexible links between the stents comprising threads or fibers. Attention is drawn to Cox et al., who teach it is known to connect stents together with threads or fibers (see figure 7E) to increase the flexibility of the prosthesis. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have replaced the weld links of Brightbill with the flexible thread links of Cox et al. to increase the flexibility of the Brightbill prosthesis.

5. Regarding claims 6 and 20, the combination of Brightbill and Cox et al. does not disclose the knot holding the threads to the stents. However, Examiner asserts the use of a specific knot would have been obvious to one of ordinary skill in the art at the time the invention was made to secure the graft to the stent.

6. **Claims 7 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brightbill (2003/0204245) in view of Cox et al. (5,824,040) as applied to claims 1 and 17 above, and further in view of McNamara et al. (6,004,347).** The combination of Brightbill and Cox et al. fails to disclose barbs extending from the stent through the graft. Attention is drawn to McNamara et al., who teach a graft disposed on the outside of a stent with a barb penetrating through the graft (see figures 10 and 11) to hold the graft onto the stent and to more securely anchor the stent against the vessel wall when deployed. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used barbs on the stents of the

combination of Brightbill and Cox et al. in the manner taught by McNamara et al. to hold the graft onto the stent and to more securely anchor the stent against the vessel wall when deployed.

### ***Response to Arguments***

7. Applicant's arguments filed 11/6/2009 have been fully considered but they are not persuasive.

8. Applicant argues the disclosed sheath or delivery matrices would be disposed on only a portion of the length of the stent does not show the claimed configuration. However, this argument is not persuasive. The end of paragraph [0023] of Brightbill clearly discloses that the invention (which is a coating on the stent) can also be embodied as a sheath-wrapped (i.e. a graft) stent covering only a portion of the length. Since the figures of Brightbill clearly show that "portion" which is coated is on at least 3 stents (illustrated as shaded in figure 1), one having ordinary skill in the art would have recognized that the shaded area region of Brightbill could be the sheath-wrapped portion.

9. Applicant also argues Cox et al. does not show the claimed structure of the links, but provides no specific reasons why. The cited links of Cox et al. are threads, therefore reading on the claim limitations. In the combination, the threads of Cox et al. would be looped around the adjacent bends in the zig zag stents of Brightbill to link the stents, thus replacing the weld links.

***Conclusion***

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

11. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan J. Severson whose telephone number is (571) 272-3142. The examiner can normally be reached on Monday - Friday 8:30-5:00.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ryan J. Severson/  
Examiner, Art Unit 3731  
2/24/10

/Anhtuan T. Nguyen/  
Supervisory Patent Examiner, Art Unit 3731  
3/1/10